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PATENT

EXPRESS MAIL LABEL NO. EL828141742US
DATE OF DEPOSIT: June 29, 2001
Attorney Reference Number 6235-59221
Application Number

**Marked-up Version of Amended Claims and Specification
Pursuant to 37 C.F.R. §§ 1.121(b)-(c)**

CLAIMS

1. (Amended) A therapeutic agent for treating a diabetic ischemic disease, [which comprises] comprising a therapeutically effective amount of a nucleic acid encoding hepatocyte growth factor (HGF) [as the effective ingredient].
2. (Reiterated) The therapeutic agent according to claim 1, used for administration to the ischemic site.
3. (Amended) The therapeutic agent according to claim 1 [or 2], wherein the diabetic ischemic disease is selected from the group consisting of diabetic lower limb ischemic disease, diabetic ischemic neuropathy [or] and diabetic ischemic myocardial infarction.
4. (Reiterated) The therapeutic agent according to claim 3, wherin the diabetic ischemic disease is diabetic lower limb ischemic disease.
5. (Amended) The therapeutic agent according to [any of claims] claim 1 [to 4, used for] wherein the administration is into the muscle of the ischemic site.
6. (Amended) The therapeutic agent according to [any of claims] claim 1 [to 5], wherein the nucleic acid encoding the HGF [gene] is in the form of a Sendai virus (HVJ)-liposome.
7. (Amended) The therapeutic agent according to [any of claims] claim 1 [to 6, which is to be administered repeatedly as needed] wherein the administration is repeated.

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8. (Amended) The therapeutic agent according to [any of claims] claim 1 [to 7],
[wherein the amount of HGF gene used is] comprising at least 50 µg of the nucleic acid encoding the
HGF.

9. (Amended) A method for the treatment of a diabetic ischemic disease, [which
comprises the transfer of the HGF gene into human] comprising administering a therapeutically
effective amount of a nucleic acid encoding hepatocyte growth factor, thereby treating the diabetic
ischemic disease.

10. (Reiterated) The method according to claim 9, wherein the HGF gene is administered
to an ischemic site.

11. (Amended) The method according to claim 9 [or 10], wherein the diabetic ischemic
disease is selected from the group consisting of diabetic lower limb ischemic disease, diabetic
ischemic neuropathy [or] and diabetic ischemic myocardial infarction.

12. (Reiterated) The method according to claim 11, wherein the diabetic ischemic disease
is diabetic lower limb ischemic disease.

13. (Amended) The method according to [any of claims] claim 9 [to 12], wherein the
nucleic acid encoding HGF [gene] is administered into the muscle of ischemic site.

14. (Amended) The method according to [any of claims] claim 9 [to 13], wherein the
HGF gene is in the form of a Sendai virus (HVJ)-liposome.

15. (Amended) The method according to [any of claims] claim 9 [to 14], wherein the
nucleic acid encoding the HGF [gene] is administered repeatedly [as needed].

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16. (Amended) The method according to [any of claims] claim 9 [to 15], wherein [the amount of HGF gene to be administered is] at least 50 µg of the nucleic acid encoding the HGF is administered to the subject.

17. (Amended) Use of [the] a nucleic acid encoding HGF [gene] for preparing therapeutic agents for diabetic ischemic disease.

18. (Amended) The use according to claim 17, wherein the diabetic ischemic disease is selected from the group consisting of diabetic lower limb ischemic disease, diabetic ischemic neuropathy [or] and diabetic ischemic myocardial infarction.

19. (Reiterated) The use according to claim 18, wherein the diabetic ischemic disease is diabetic lower limb ischemic disease.

20. (Amended) The use according to [any of claims] claim 17 [to 19], wherein the nucleic acid encoding HGF [gene] is in the form of a Sendai virus (HVJ)-liposome.

21. (Amended) The use according to [any of claims] claim 17 [to 20], wherein the amount of the nucleic acid encoding the HGF [gene to be used] is at least 50 µg.